FSN Ref: 2019-12 (02)
Date: 26 Feb 2020

FSCA Ref: 2019-12 (02)

Urgent Field Safety Notice
Mölnlycke® Procedure Trays

For Attention of: Theatre Manager

Contact details of local representative (name, e-mail, telephone, address etc.)
Name: Local Customer Care contact will be added for each specific market Email: XXX.XXX@molnlycke.com Telephone: +XXXXXXXXXXXXX

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Urgent Field Safety Notice (FSN)
Mölnlycke® Procedure Trays
Protective flanges coming away from trocar cannula included in Mölnlycke® Procedure Trays

	1. Information on Affected Devices
1.	1. Device Type(s)
	Components: Optical Trocar 12mm / 100mm, Mölnlycke component code 2319428-00  Universal Trocar Cannula 12mm / 100mm, Mölnlycke component code 2319467-00  Included in various Mölnlycke® Procedure Trays Mölnlycke® Procedure Trays consist of customized configurations of components, which are assembled and delivered sterile within one packaging solution.
1.	2. Commercial name(s)
	See Appendix I Product Table
1.	3. Primary clinical purpose of device(s)
	A trocar consists of an obturator and a cannula that are assembled and locked together during insertion through the abdominal wall tissue layers to create a port to the abdominal cavity. The Optical Trocar is a sterile single patient use device. The trocar is designed to establish a port of entry for endoscopic instruments during minimally invasive surgical procedures. The secondary function is to maintain pneumoperitoneum in the abdominal cavity. The Optical Trocar can be used with or without visualization for primary and secondary insertions. The Universal cannulas, included in the trocar range, are seen as accessories since they can't be used without using an obturator from the trocar. The clinical purpose of Mölnlycke® Procedure Trays is to provide a customized sterile co-packing of components for different clinical interventions.
1.	4. Device Model/Catalogue/part number(s)
	See Appendix I Product Table
1.	5. Affected serial or lot number range

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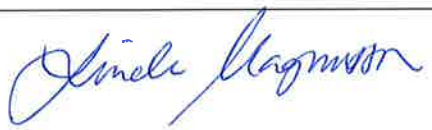
	See Appendix I Product Table

	2 Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem*
	Mölnlycke has, through our product complaint system, become aware of situations where the protective flanges come away from trocar cannula. Mölnlycke is initiating a Field Safety Corrective Action on specific batches of the trocar and trocar cannula, which Mölnlycke includes in some of the Mölnlycke® Procedure trays.
2.	2. Hazard giving rise to the FSCA*
	The reported incidents are potentially serious to patients as the disconnected flanges could cause a significant delay to surgery. When not retrieved, foreign bodies can lead to various post-operative complications and the need for a new surgery. No injury to patient has been reported.

	3. Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Destroy Device Please use the information in the **Product Table** in **Appendix I** to identify all affected, unused Mölnlycke® Procedure trays at your facility. Please follow below instructions: 1. Attach this **Field Safety Notice** (FSN) to the Mölnlycke® Procedure trays stated in **Appendix I**. At the point of use, the user is required to remove the affected devices (components) from the Mölnlycke® Procedure trays, destroy them and following this, update the amount of trays from which affected devices (components) have been destroyed in the Appendix II **Customer Reply Form**. 2. Once all affected trays have been utilized, and all affected devices (components) are destroyed, please **sign** and **email/fax** the Customer Reply Form or Distributor Reply Form per its instructions. 3. Fill out the **Customer Reply Form** (Appendix II) or **Distributor Reply Form** (Appendix III), and return it back within 10 business days, (even if you no longer have any concerned Mölnlycke® Procedure trays). Mölnlycke needs to be sure all customers are aware of the situation. 4. When completed and signed **Customer Reply Form** or **Distributor Reply Form** is received by Mölnlycke, Mölnlycke will contact you regarding compensation for the affected components destroyed. 5. If you have forwarded any affected products to other healthcare institutions, please send them a copy of this **Field Safety Notice**. Make sure they act accordingly. 6. If you are a distributor, please inform your customers by sending them a copy of this **Field Safety Notice**. Make sure they act accordingly. Please return the **Distributor reply form** in **Appendix III** to Mölnlycke.

	In addition, Mölnlycke appreciates your help in collecting data on product complaints and/or incidents related to the concerned product. Please follow the reporting procedures established by your facility.	
3.	2. Is customer Reply Required?	Yes (Within 10 business days)

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Mölnlycke Health Care AB
	b. Address	Box 130 80, SE-402 52 Gothenburg, Sweden
	c. Website address	www.molnlycke.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Appendix I Product table Appendix II Customer Reply Form Appendix III Distributor Reply Form
4.	6. Name/Signature	Linda Magnusson, Post Market Surveillance and Site Quality Director 

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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Appendix I

Product table

To be added for each market

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Appendix II

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2019-12 (02)
FSN Date	26 Feb 2020
Product/ Device name	See Appendix I Product table
Product Code(s)	See Appendix I Product table
Batch/Serial Number (s)	See Appendix I Product table

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation			
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		N/A	Comments:
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. I do not have any affected devices.		
Print Name*			
Signature*			
Date*			

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4. Return acknowledgement to sender	
Email	vigilance@molnlycke.com
Customer Helpline	+XXXXXXXXXXXXX
Postal Address	Mölnlycke Health Care, Box 130 80, SE-402 52 Gothenburg, Sweden
Fax	+46 31 722 34 00
Deadline for returning the customer reply form*	Within 10 days

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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Appendix III

Distributor Reply Form

5. Field Safety Notice (FSN) information	
FSN Reference number*	2019-12 (02)
FSN Date*	26 Feb 2020
Product/ Device name*	See Appendix I Product table
Product Code(s)	See Appendix I Product table
Batch/Serial Number (s)	See Appendix I Product table

6. Distributor Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

7. Return acknowledgement to Sender	
Email	Pre-filled by manufacturer/sender/requester
Distributor Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Deadline for returning the Distributor reply form*	Pre-filled by manufacturer/sender/requester

8. Distributors (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined inventory	
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	

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☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		N/A	Comments:
☐	Neither I nor any of my customers has any affected devices in inventory		
Print Name*			
Signature*			
Date *			

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.